Oversight and Investigations Subcommittee
"The Heparin Disaster: Chinese Counterfeits and American Failures"
April 29, 2008

Leroy Hubley Statement

Mr. Chairman and Members of the Committee:

Thank you very much for inviting me to testify at today's important hearing. My name is Leroy Hubley and I am from Toledo, Ohio.

My wife, Bonnie, died in December after receiving Heparin that was later recalled by Baxter. My son, Randy died a month later under similar circumstances. I hope that by telling their stories it will bring us all closer to answer the questions that families like mine desperately seek.

Bonnie was my wife of 48 years. She had a genetic disease known as polycystic kidney disease or "PKD." This disease affects the kidneys. Specifically, cysts grow in the kidneys. If too many cysts grow or if they get too big, the kidneys become damaged. All of my children also have this disorder.

Bonnie received a kidney transplant in 1995. Last year my wife's body started to reject her kidney. As a result, she had to start hemodialysis in October of 2007. At first, the dialysis sessions were uncomplicated.

But in December of 2007, she began to experience unusual symptoms during and after dialysis. She developed diarrhea, vomited and felt like her heart was beating out of control while on dialysis. Then, during dialysis on December 17, 2008, she developed pain in her chest and abdomen and the clinic needed to call an ambulance.

Bonnie was rushed from the dialysis clinic to Toledo Hospital. While at the hospital she had a drop in blood pressure, difficulty breathing, severe diarrhea and rapidly declined. Three days later on December 19, 2007, the doctors recommended removing her breathing tube to end her suffering. Her entire family, our son, daughters, in-laws, and grandchildren were all there. As Christmas music softly played in the background, we each said our goodbyes. Then my wife and love of 48 years drifted away.

We did not realize at that time that the heparin she received may have been tainted. We simply tried to deal with the grief that follows the loss of a loved one.

However, the nightmare returned only weeks later, when my son Randy, returned home to Toledo following a surgery at the Cleveland Clinic. On January 7, 2007, he started dialysis at the same Fresenius clinic in Toledo as Bonnie. Randy had been receiving hemodialysis for approximately eight months before at other locations. However, as you will hear my daughter in law Colleen Hubley describe, when Randy started dialysis at the Toledo Fresenius Clinic, he too developed nausea, low blood pressure, abdominal pain, fatigue and diarrhea. About a week later, my 47 year old son was dead, leaving behind his own three children and a grandchild.

Again, we attributed his death to a cruel twist of fate. That was, until we found out about the January recall of heparin. When we contacted the dialysis center, they confirmed our fear, that the heparin given to our loved ones had in fact been recalled by Baxter.

Now I am left to deal not only with the pain of losing my wife and son, but anger that an unsafe drug was permitted to be sold in this country. The FDA and Baxter have

not done their job. I want to know what is going to be done to rectify the matter. I want to know if my daughter, Dawn, and the millions of others who continue to receive dialysis, are safe.

I want to thank the scientists and doctors who have found the link between the counterfeit heparin and these deaths.[1] I hope that the members of this committee will take steps to protect us all and make it right.

Respectfully Submitted,

Leroy Hubley
Toledo, Ohio

[1] Contaminated Heparin Associated with Adverse Clinical Events and Activation of the Contact System, Kishimoto, *et al*, new England Journal of Med 2008;358, published at www.nejm.org on April 23, 2008.